Supreme Court, U.S.
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No. 97-337

In The

Supreme Court of the United States

October Term, 1996

GENENTECH, INC.,

Petitioner,

vs.

NOVO NORDISK A/S, NOVO NORDISK OF NORTH AMERICA, INC. and NOVO NORDISK PHARMACEUTICALS, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENTS' BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

Respondents object to the Questions Presented because they incorrectly assert that the Federal Circuit disregarded settled law and the text of 35 U.S.C. § 112 and adopted a new test for enablement that the Federal Circuit did not in fact adopt.

Contrary to Question 1, the Federal Circuit did not rule that "a patent specification must state what is already known in the art." Nor did the Federal Circuit, as is stated in Question 1a, rule "that information well known in the art may be used only to 'supplement' a patent specification with 'minor details.' " Since the Federal Circuit did not make these rulings, Question 1b, whether the decision below will "call into question the validity of thousands of issued patents," "lead to a substantial increase in the length of patent specifications," and "diminish the ability of inventors to obtain meaningful patent coverage," is also objectionable, and improperly uses hyperbole to seek this Court's review of mere conjecture. It is based on the incorrect premise that the Federal Circuit changed long-standing precedent.

Respondents also object to Petitioner's formulation of Question 2 because it wrongly assumes that the Federal Circuit's decision was premised on the resolution of "disputed issues of fact," rather than on a *de novo* determination of a controlling issue of law.

PARTIES TO THE PROCEEDING

The parent companies, subsidiaries (except wholly owned subsidiaries), and affiliates, that have issued shares to the public, of the Respondents are: Novo Nordisk A/S.

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Respondents (hereinafter collectively "Novo Nordisk"), respectfully oppose the prayer of Petitioner (hereinafter "Genentech") that a writ of certiorari issue to review the Judgment and Opinion of the United States Court of Appeals for the Federal Circuit, dated March 13, 1997 (Appendix A).

STATEMENT OF THE CASE

A. Having Twice Failed Before The Federal Circuit To Enforce Improvidently Granted Preliminary Injunctions Against Novo Nordisk, Genentech Now Turns To This Court To Resolve This Private Dispute.

The dispute between Novo Nordisk and Genentech before the United States District Court for the Southern District of New York resulted in two successive preliminary injunctions against Novo Nordisk. Both preliminary injunctions were vacated by the Federal Circuit. The Petition seeks review of the Federal Circuit's vacatur of the second injunction.

The first preliminary injunction (issued on June 28, 1995), based on Genentech's U.S. Patent 4,601,980 (the " '980 patent"), was vacated by the Federal Circuit on February 26, 1996. *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, 77 F.3d 1364 (Fed. Cir. 1996) ("*Novo I*"). The second preliminary injunction (issued on June 27, 1996), based on Genentech's related U.S. Patent 5,424,199 (the " '199 patent"), was vacated by the Federal Circuit on March 13, 1997. *Genentech, Inc. v. Novo Nordisk, A/S et al.*, 108 F.3d 1361 (Fed. Cir. 1997) ("*Novo II*") ("Decision") (Appendix A). *Novo I* did not reach the issue of the validity of the '980 patent. *Novo II* held that the '199 patent was invalid for failing to meet the enablement requirement of 35 U.S.C. § 112, ¶ 1.

B. Although The Parent Application Of The '199 Patent Was Filed In 1979, Claims To Enzymatic Cleavable Fusion Expression Of Human Growth Hormone Were Not Presented Until 1989.

The '199 patent issued from the last of a series of continuing patent applications that began with the filing by Genentech of a "parent" patent application in 1979. According to 35 U.S.C. § 112, ¶ 2, a patent applicant must assert "claims" for the subject matter "which the applicant regards as his invention." However, it was not until 1989, ten years after the filing of the 1979 parent application, that claims were first presented to enzymatic cleavable fusion expression of hGH.[1] The undisputed record is that Genentech never made hGH by enzymatic cleavable fusion expression prior to the filing of the parent application in July 1979. The Decision clearly recognized that the '199 patent is nothing more than a means by which Genentech impermissibly seeks to bootstrap a claim to an invention which it neither made nor has any rights therein:

> [T]he specification for the '199 patent, which is the same as the specification for the '980 patent, does not provide a specific enabling disclosure concerning what the new claim recites, *viz*, obtaining hGH by cleaving an hGH-containing protein. That was the problem avoided by the invention claimed in the '980 patent. The present specification contains no more disclosure than the '980 specification, but this patent now purports to claim the unresolved problem that the '980

1. The enablement requirement must be fulfilled for the '199 patent as of the 1979 filing date of the parent application. *In re Glass*, 492 F.2d 1228, 1232 (CCPA 1974). *See also* 35 U.S.C. § 120.

> patent overcame. *Genentech is attempting to bootstrap a vague statement of a problem into an enabling disclosure sufficient to dominate someone else's solution of the problem. This it cannot do.*

(Appendix A at 9) (emphasis added).

C. The Holding Of Lack Of Enablement Of The '199 Patent Was Foreshadowed In *Novo I*.

The holding in *Novo II* that the '199 patent specification did not enable the enzymatic cleavable fusion expression of hGH was foreshadowed in *Novo I*. The issue whether the '980 patent specification, *which is identical to that of the '199 patent specification*, enabled enzymatic cleavable fusion expression was raised in *Novo I*, but was unnecessary to decide because the Federal Circuit determined that the patent did not claim cleavable fusion expression. However, in *Novo I*, the Federal Circuit did express its doubt as to whether Genentech could assert a claim to the production of hGH by enzymatic cleavable fusion expression, because the '980 patent specification "contained little, if any, specific disclosure" as to the production of hGH by that process:

> Genentech consistently argued during prosecution that the patentable invention was a method of directly expressing human growth hormone; it never argued that the invention included cleavable fusion expression.
>
> * * *
>
> As a practical matter, Genentech's retreat during prosecution from its reference to

> cleavable fusion expression is unsurprising, given the numerous PTO rejections of the claims as unpatentable over known fusion protein processes, *and the fact that the '980 specification contains little, if any, specific disclosure of how to obtain the expression product by cleavable fusion expression.* It appears that Genentech wrote a broader disclosure, but settled for patent protection for its preferred embodiment.

77 F.3d at 1370, n.8 (citations omitted) (emphasis added).

Unimpressed by the Federal Circuit's statement that the '980 specification, and hence the identical '199 specification, contained "little, if any, specific disclosure" regarding claim to cleavable fusion expression, Genentech moved quickly, after the *Novo I* preliminary injunction was vacated, for another preliminary injunction based on the alleged infringement of the '199 patent. The second preliminary injunction was granted by the district court. On appeal to the Federal Circuit, the *Novo II* court vacated the second preliminary injunction, and held the '199 patent invalid under 35 U.S.C. § 112, ¶ 1, as a matter of law, because its specification failed to enable those skilled in the art how to make and use the full scope of the claimed enzymatic cleavable fusion expression invention without undue experimentation. (Appendix A at 6).

Having been told twice by the Federal Circuit that the '199/'980 patent specification does not satisfy the enablement requirement of 35 U.S.C. § 112, ¶ 1, Genentech now turns to this Court for assistance in its baseless quest to enjoin Novo Nordisk from selling hGH in the United States. As detailed below, there is no cause for this Court's review of this controversy.

REASONS FOR DENYING THE WRIT

The Petition must be denied because if fails to raise questions of patent law that are important to persons other than the parties, or that impact other patents. *Layne & Bowler Corporation v. Western Well Works*, 261 U.S. 387, 393 (1923). Moreover, the decision of the Federal Circuit in *Novo II* was correct.

Enablement is a question of law that is reviewed independently by the court of appeals. Applying properly stated, long-standing rules of patent law, and after a careful review of the complete factual record, the Federal Circuit vacated the preliminary injunction in *Novo II* because the '199 patent specification contained no details whatsoever concerning how to carry out the claimed invention, and thus failed to enable one skilled in the art to make and use the full scope of the claimed invention without undue experimentation. Accordingly, the Federal Circuit held, as a matter of law, that the '199 patent was invalid. (Appendix A at 5-6).

The Petition also fails to raise an important question concerning the Federal Circuit's determination of invalidity of the '199 patent under 35 U.S.C. § 112, ¶ 1, on the merits, pursuant to 28 U.S.C. § 2106. After a twelve-day evidentiary hearing before the district court, during which many witnesses testified for each side on the enablement issue, the factual record was "full and complete," and the issues "thoroughly ventilated." Novo Nordisk represented to the Federal Circuit, during oral argument, that it would not introduce new evidence on the issue of enablement and Genentech represented to the Federal Circuit, also during oral argument, that it would introduce new evidence "only in response to new arguments and new defenses raised by Novo." The issue of enablement was therefore ready for final decision. (Appendix A at 12-13).

I.

THE DECISION CORRECTLY STATED AND APPLIED LONG-STANDING PRECEDENT CONCERNING THE LAW OF ENABLEMENT.

No cause exists for this Court's review of the Decision holding that the '199 patent failed to satisfy the requirements of 35 U.S.C. § 112, ¶ 1. It is beyond debate that the correct standard of law was applied by the Federal Circuit in invalidating the '199 patent.

Whether a patent disclosure is enabling pursuant to 35 U.S.C. § 112, ¶ 1, is a legal issue that is reviewed by the Federal Circuit *de novo*. *See Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1268 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987); *see also In re Goodman*, 11 F.3d 1046, 1049-1050 (Fed. Cir. 1993) ("Whether Goodman's specification satisfies 35 U.S.C. § 112's enablement requirement is a question of law which this court reviews independently."). Factual issues underlying the legal issue whether a claimed invention is enabled are reviewed by the court of appeals for clear error. *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991). Citing its own precedents, the Federal Circuit properly stated the correct rule of law concerning enablement:

> [T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the *full scope of the claimed invention without 'undue experimentation.' In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharm, Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher*, 427 F.2d 833, 839, 166

> USPQ 18, 24 (CCPA 1970) ("*[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification* to persons of ordinary skill in the art.").

(Appendix A at 6) (emphasis added).

II.

DESPITE THE BROAD SCOPE OF THE CLAIM OF THE '199 PATENT, THE SPECIFICATION, AS THE FEDERAL CIRCUIT HELD, "DOES NOT DESCRIBE IN ANY DETAIL WHATSOEVER HOW TO MAKE hGH BY ENZYMATIC CLEAVABLE FUSION EXPRESSION" AND HENCE, AS A MATTER OF LAW, THE '199 PATENT IS INVALID.

Claim 1 of the '199 patent is of extremely broad scope. On its face, it seeks to encompass the expression of any fusion or conjugate protein comprising hGH fused to any amino acid sequence, and the use of any enzyme that will cleave the amino acid sequence from the conjugate protein to provide 1-191 amino acid hGH. (Appendix A at 2-3). It has long been the law that a patent claim with such broad scope must be supported by a patent specification with a commensurate degree of disclosure to meet the enablement requirement under 35 U.S.C. § 112, ¶ 1. *See Amgen, Inc.*, 927 F.2d at 1212 ("The essential question here is whether the scope of enablement of claim 7 is as broad as the scope of the claim."); *In re Wright*, 999 F.2d at 1561 (citing *In re Fisher*, 427 F.2d at 839 ("the first paragraph of section 112 requires that the scope of protection sought in a claim bear a reasonable correlation to the scope of enablement provided by the specification.")). Both *Amgen* and *Wright* were cited in the Decision for this very same principle. (Appendix A at 6). *See also In re Goodman*, 11 F.3d at 1050 ("Naturally, the

specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed."); *In re Vaeck*, 947 F.2d at 495-496 ("There is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria . . . . Accordingly, we affirm the § 112 rejection as to those claims.").

Claim 1 also broadly claims "the application of an unpredictable technology in the early stages of development." (Appendix A at 12). Patents that claim subject matter in undeveloped or unpredictable fields, such as biotechnology and pharmaceuticals, are held to a well-established higher enablement standard under 35 U.S.C. § 112, ¶ 1. *In re Vaeck*, 947 F.2d at 496 (limited disclosure found not enabling for an unpredictable art); *In re Fisher*, 427 F.2d at 839 ("In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement varies inversely with the degree of unpredictability of the factors involved."). The court in *Vaeck* thus explained:

> It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. [citation omitted]. However, there must be sufficient disclosure, either through illustrative examples or terminology, *to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility.* Where, as here,

> a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element.

947 F.2d at 496 (emphasis added).

Notwithstanding its broad claim to an unpredictable and undeveloped biotechnology, the '199 patent specification contains *no* details whatsoever to guide the art worker to practice the enzymatic cleavable fusion expression of hGH. The Federal Circuit thus held as a matter of law:

> *There is no dispute that the portion of the specification chiefly relied upon by Genentech and by the district court, column 7, lines 29-59, does not describe in any detail whatsoever how to make hGH using cleavable fusion expression.* For example, no reaction conditions for the steps needed to produce hGH are provided; no description of any cleavable conjugate protein appears.

(Appendix A at 6-7) (emphasis added). Consequently, the Federal Circuit also held, as a matter of law, that:

> [R]easonable detail must be provided in order to enable members of the public to understand and carry out the invention. That requirement has not been met *in this*

> *specification* with respect to the cleavable fusion expression of hGH.

(Appendix A at 8) (emphasis added).

III.

UNABLE TO DENY THAT THE FEDERAL CIRCUIT APPLIED THE CORRECT RULE OF LAW, GENENTECH MISREPRESENTS THE DECISION AND TRIES TO SHOW THAT THE FEDERAL CIRCUIT ESTABLISHED A NEW RULE OF LAW.

Genentech concedes that the '199 patent specification does not describe in any detail whatsoever how to make hGH using enzymatic cleavable fusion expression. (Appendix A at 6). It argues in response, however, that the Federal Circuit departed from the rule that a specification need not disclose what is well-known in the art. (Petition at 5-7). However, the Federal Circuit took full cognizance in its Decision of the rule that "a specification need not disclose what is well known in the art," properly citing that rule and its precedent, *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986), *cert denied*, 480 U.S. 947 (1987). (Appendix A at 8). Genentech thus misrepresents the Decision by using "[citations omitted]" in its quotation taken from the Decision, thereby misleadingly suggesting that the Federal Circuit failed to apply established precedent in judging Genentech's specification. (Petition at 7).

In addition, Genentech fails to come to grips with the fact that enzymatic cleavable fusion expression of hGH was *not* well-known in the art in 1979.[2] After reviewing the record developed in the district court, the Federal Circuit concluded that

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2. Indeed, if the cleavable fusion expression of hGH had been known to others within the art, the process claimed in the '199 patent would not have been patentable to Genentech under 35 U.S.C. §§ 102 and/or 103.

> This failure of skilled scientists, who were supplied with the teachings that Genentech asserts were sufficient and who were clearly motivated to produce human proteins, indicates that producing hGH via cleavable fusion expression was not then within the skill of the art.

(Appendix A at 10-11).

As the specification of the '199 patent did "not describe in any detail whatsoever how to make hGH using cleavable fusion expression," (Appendix A at 6), the Federal Circuit was then correct in holding, as a matter of law, that the patent was not enabled.[3] Because the '199 patent specification "*does not describe in any detail whatsoever* how to make hGH using [enzymatic] cleavable fusion expression," (Appendix A at 6) (emphasis added), the Federal Circuit was further correct in holding, as a matter of law, that the gross inadequacies of the specification could not be remedied through the wholesale substitution of an expert's retrospective and hypothetical creation of the claimed process. (Appendix A at 10). Accordingly, since as a matter of law the specification of the '199 patent is inadequate to provide an enabling disclosure for the full scope of claim 1, conclusory expert testimony on the ultimate issue of

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3. The Federal Circuit also held that the district court's findings on enablement were not supported by the record. For example, the record of the preliminary injunction hearing did not support the district court's finding that hGH could be produced in useful form, and instead indicated that determination of how to obtain hGH by cleavable fusion expression "required further undue experimentation." (Appendix A at 11). Thus, the preliminary injunction was properly vacated because of the district court's clear error of judgment in weighing relevant factors, or its clearly erroneous factual findings. *Joy Tech., Inc. v. Flakt, Inc.*, 6 F.3d 770, 772 (Fed. Cir. 1993). (Appendix A at 4).

enablement is irrelevant. (Appendix A at 11, citing *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991)).

In each of this Court's precedents cited by Genentech, (Petition at 5), the patent-in-suit did contain a detailed description of the claimed invention. None involved, as here, a patent that contained no details whatsoever regarding the claimed invention. Hence, these cases do not aid Genentech.

Thus, *Lawther v. Hamilton*, 124 U.S. 1, 9 (1888), involved a three-step process, where "[e]very step of this process was already understood, although not connected in the manner pointed out in the patent." 124 U.S. at 9. In *Webster Loom Company v. Higgins*, 105 U.S. 580 (1881), the patent contained a detailed description of the invention, and the defendants even acknowledged that the elements of the claimed machine were well known. 105 U.S. at 587. Hence, the patent was clearly enabled. In *Minerals Separation v. Hyde*, 242 U.S. 261 (1916), the patent specification described in detail a process for treating ores with oil, but did not specify the precise treatment required for each ore. 242 U.S. at 271. The Court explained that it was acceptable to leave "something to the skill of persons applying the invention." *Id.* at 271. In each of these cases, only minor details were omitted from the specification, details that were well-known to the skilled worker.

The Federal Circuit did not depart from this Court's or its own precedents, by explaining that while "well-known" information need not be disclosed in the specification, this is merely "a rule of supplementation," allowing a patent application to omit minor details. While this rule permits the application to leave "*something* to the skill of persons applying the invention," *Minerals Separation*, 242 U.S. at 271 (emphasis added), it cannot be "a substitute for basic enabling disclosure." (Appendix A at 8). Thus, where as here, the specification utterly lacks an

enabling disclosure, the patent must fail, because "the specification, not the knowledge of one skilled in the art . . . must supply the novel aspects of an invention in order to constitute adequate enablement." (Appendix A at 8-9).

Indeed, it simply makes sense to say that the "novel aspects" of an invention cannot be "well-known information" to those of ordinary skill at the time of a purportedly new invention. To say the opposite, as Genentech's urges, is to say that the "novel aspects" of a claimed new invention can at the same time be "well-known information," which stands the logic of patent law on its head. *See* 35 U.S.C. §§ 102, 103. The Federal Circuit's reference to "novel aspects" was therefore not a formulation of a new rule of enablement. Rather, it was the court's expression of a common sense rejection of Genentech's argument that it could substitute for the lack of "any detail whatsoever [of] how to make hGH by cleavable fusion expression," (Appendix A at 6), the conjectures of an expert trial witness (speaking with the benefit of nearly 20 years' hindsight), that enzymatic cleavable fusion expression of hGH, a technology Genentech claims to have invented in 1979, could have been developed by others in 1979.

After setting up the strawman that the Federal Circuit promulgated a "point of novelty" test for enablement, Genentech refers to a number of Federal Circuit precedents that have rejected the "point of novelty" test as the standard of non-obviousness under 35 U.S.C. § 103, and says that, by force of analogy, the purported "novel aspects" test should be rejected here. (Petition at 8). This argument is too facile to work. By referring to the "novel aspects" of the '199 specification, the Federal Circuit was not adopting a "point of novelty" test, but was merely explaining why the absence in the specification of any details whatsoever of how to make hGH by enzymatic cleavable fusion expression was a fatal defect that could not be cured by expert testimony.

Having held that the specification of the '199 patent contains *no* disclosure to instruct the art worker how to practice the enzymatic cleavable fusion expression of hGH, the Federal Circuit provided several examples of what was missing from the '199 patent:

- no description of reaction conditions for the steps needed to enzymatically cleave a conjugate protein (Appendix A at 8, 10);

- no description of any specific cleavable protein from which hGH could be obtained (Appendix A at 8, 10);

- no suggestion of "a single amino acid sequence, out of the virtually infinite possibilities that would yield hGH in a useful form" (Appendix A at 8); and

- no actual or prophetic example in the patent specification (Appendix A at 11).

These illustrations of what is missing from the specification are not new requirements for an enabling disclosure, as Genentech stridently asserts, (Petition at 8-9), but rather reflect the Federal Circuit's determination that, in an unpredictable and underdeveloped science,

> [W]hen there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required . . . .

(Appendix A at 8).

Genentech further argues that the Federal Circuit applied a subjective test for enablement by ruling that the '199 patent

should have disclosed standard reaction conditions for known enzymes. (Petition at 9). The court made no such ruling.[4] The reaction conditions necessary for the enzymatic cleavable fusion expression of hGH were *not* well known. The record merely indicated that while *general* routine methods for the *digestion* of proteins (*i.e.*, breaking proteins into pieces or fragments) were disclosed in a textbook reference, that text did not teach how to specifically and precisely cleave conjugate proteins to yield *intact*, useful proteins. (Appendix A at 7-8). In addition, the British patent relied upon by Genentech to supplement its disclosure indicated that the only disclosed enzyme that *might* be used, trypsin, would not be useful for the cleavable fusion expression of proteins such as hGH. The Federal Circuit correctly observed:

> This specification [of the British patent] is so lacking with respect to the limitation of paragraph (b) of claim 1 that providing testimony regarding the skill of the art has been an exercise in futility.

(Appendix A at 11). Further, neither the '199 patent nor Genentech's extrinsic references even suggested "a single amino acid sequence, out of the virtually infinite range of possibilities, that would yield hGH in a useful form when cleaved from the conjugate protein." (Appendix A at 7-8).

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4. The Petition states that the "Decision states *definitively and without qualification* that *a* failure to disclose *a* starting material or process condition . . . leads to the *unwavering conclusion* that the patent is not enabled . . . ." (Petition at 9, n.2) (emphasis added). Here, Genentech has again misrepresented the language of the Decision. The quote from the Decision is properly: "when there is no disclosure of *any* specific starting material or of *any* of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art." (Appendix A at 8) (emphasis added).

IV.

GENENTECH'S UNSUPPORTED HYPERBOLE OF DIRE CONSEQUENCES TO THE PATENT SYSTEM SHOULD BE DISREGARDED.

Genentech predicts that the Decision will cause "irreparabl[e] harm . . . by promoting inconsistent district court decisions and unreliable PTO actions," and that patent specifications will now be of "enormous length" because inventors are now allegedly required to repeat the prior art. (Petition at 9-10).

Genentech's prediction is wholly unsupported by the record and reason. Nothing in the Decision requires patent applicants, past or present, to "repeat the prior art" in their applications. The Decision holds that Genentech failed to meet the enablement requirement by failing to disclose in the specification "any detail whatsoever how to make hGH by cleavable fusion expression." (Appendix A at 6). In fact, according to the standard practice of patent attorneys noted by the Federal Circuit, if Genentech knew how to produce hGH by enzymatic cleavable fusion expression, such a process would have been disclosed, not omitted, from the specification:

> [I]t stands to reason that if the disclosure of a useful conjugate protein and the method for its cleavage were so clearly within the skill of the art, it would have been expressly disclosed in the specification, and in the usual detail. Patent draftsmen are not loath to provide actual or constructive examples, with details, concerning how to make what they wish to claim.

(Appendix A at 11). The fault with the '199 patent lies in Genentech's failure to describe "in any detail whatsoever how to make hGH using cleavable fusion expression." (Appendix A at 6).

V.

THE FEDERAL CIRCUIT WAS CORRECT IN ADJUDICATING AND DISMISSING GENENTECH'S CLAIMS ON THE MERITS BY HOLDING THE '199 PATENT INVALID AFTER TWO LENGTHY PRELIMINARY INJUNCTION HEARINGS.

In a baseless attempt to manufacture a question of great public importance in a dispute that presents none, Genentech argues that the Federal Circuit's decision vacating the preliminary injunction and holding the '199 patent invalid for failing to meet the enablement requirement "changed the function of an appellate court." (Petition at 10). Genentech further asserts that the court "conducted a trial at the appellate level," deprived it of "due process," and denied "its opportunity to present a complete trial record." (*Id.*). Genentech is simply wrong on the facts and the law, however, because the Federal Circuit — deciding an issue of law on a record that Genentech's counsel conceded was complete as to that issue — properly exercised its authority under 28 U.S.C. § 2106 in vacating the preliminary injunction and determining that Genentech's patent was invalid as a matter of law.

VI.

CONTRARY TO GENENTECH'S ASSERTIONS, THE FEDERAL CIRCUIT ACTED UPON A COMPLETE RECORD WHEN IT HELD THE '199 PATENT TO BE INVALID.

The Federal Circuit had the power to make a final determination on the defense of invalidity because it had a full and complete record before it. *See Susquehanna Corp. v. Pan American Sulphur Co.*, 423 F.2d 1075, 1086 (5th Cir. 1970). In the Petition, Genentech misleadingly omits the following representations of counsel made in response to Judge Bryson's questions concerning the record below on enablement during the oral hearing of this appeal before the Federal Circuit:

> Mr. Jacobs [counsel for Novo Nordisk responding to Judge Bryson]:
>
> > This court has a very full and complete record before it. It's hard to imagine any significant additional evidence being adduced at the full trial on the merits. So this court really has the benefit of everything it really needs to have.
>
> * * *
>
> Judge Bryson: [to Ms. Ben-Ami]
>
> > I don't want to bind you to a concession, but you started out by saying that you thought Novo would like to produce different evidence, would like to re-try the case I think

> that was your characterization. Is there anything you would introduce at trial other than what you have introduced during the twelve days of preliminary injunction here?

Ms. Ben-Ami [counsel for Genentech]:

> Yes. *As to the issues that weren't raised below that they are trying to raise on appeal.*

Judge Bryson:

> I see, but the ones that are before us, for example, written description, enablement.

Ms. Ben-Ami [counsel for Genentech]:

> There might be. There might be. Because, while we have had discovery from a prior ITC proceeding, when you're plaintiff in a patent case you really need to look at what the defendant's defenses are and then plan accordingly. *We were given you know, a limited number of defenses that Novo was going to raise and if they were to change their positions or add to their positions, which is something they could do, we would have to have that ability at some point to put in other evidence.*

(Audio tape of oral argument before the Federal Circuit, dated December 5, 1996 (emphasis added)).

Based on the above representations, the Federal Circuit was correct to note that "Genentech stated that it would introduce new evidence at a full trial only in response to new arguments and new defenses raised by Novo." (Appendix A at 12, n.5). After a twelve-day preliminary injunction hearing in *Novo II*, and a prior thirteen-day evidentiary hearing in *Novo I* on the identical patent specification, the Federal Circuit was also correct in concluding that "the parties agreed at oral argument that the issue had been thoroughly ventilated," and that it was therefore "appropriate to rule on Novo's defense of invalidity" pursuant to 28 U.S.C. § 2106. (Appendix A at 12). The preliminary injunctions in both *Novo I* and *Novo II* were issued after lengthy hearings at which expert and fact witnesses testified for several days, hundreds of exhibits were introduced, and extensive arguments were presented by counsel for the parties — all of which amounted to twenty-five (25) days of evidentiary hearings on the identical '199 and '980 patent specifications.

Importantly, the Federal Circuit held that the district court "abused its discretion by granting the preliminary injunction based upon an *error of law*." (Appendix A at 13) (emphasis added). As a matter of law, and after its *de novo* review, the court held the '199 patent invalid for failure to meet the enablement requirement of 35 U.S.C. § 112. *See Moleculon Research Corp.*, 793 F.2d at 1268. Genentech knew the legal standard of review on this issue when it briefed and argued the appeal, and when it agreed that it would present evidence at trial "only as to new arguments and new defenses raised by Novo," Genentech permitted the Federal Circuit to decide the enablement issue on the merits. After twenty-five (25) trial days, both parties agreed that there was not much left to say about enablement. That the ultimate decision was unfavorable to Genentech would seem to be the only motivation for Genentech to *now* say the record is "incomplete."

Genentech also asserts that the Federal Circuit made and substituted its own fact findings for those of the district court. (Petition at 11-13). It did not. After a thorough review of the record, the Federal Circuit held that the established facts concerning the knowledge of one skilled in the art at the time of the effective date of the '199 application, July 1979, did not support the conclusion that enzymatic cleavable fusion expression, an emerging technology, was well known in 1979, and that, as a matter of law, the '199 specification did not enable the claim to cleavable fusion production of hGH. The Federal Circuit correctly held that the specification did "not describe in any detail whatsoever how to make hGH using cleavable fusion expression." (Appendix A at 6-7).

All of these facts were in the record of the district court and were reviewed, not "found" or "resolved," by the Federal Circuit. Because the '199 patent was devoid of any details whatsoever concerning the claimed process, the Federal Circuit held, as a matter of law, that the '199 patent specification lacked an enabling disclosure such that the hindsight expert testimony offered by Genentech could not save it. Genentech's disagreement with the Federal Circuit's review of the record is not cause for review by this Court.

VII.

THE FEDERAL CIRCUIT HAD AUTHORITY UNDER 28 U.S.C. § 2106 TO ENTER JUDGMENT AGAINST GENENTECH AFTER THE EXTENSIVE PRELIMINARY INJUNCTION HEARING.

The Federal Circuit properly adjudicated Novo Nordisk's defense of invalidity on the merits under the statutory authority of 28 U.S.C. § 2106, which provides, in pertinent part:

> The Supreme Court or any other court of appellate jurisdiction may . . . direct the entry of such appropriate judgment, decree, or order, or require such further proceedings to be had *as may be just under the circumstances.*

28 U.S.C. § 2106 (emphasis added). Section 2106 grants appellate courts broad discretion in the disposition of a case on appeal. *See Susquehanna Corp.*, 423 F.2d at 1086. Indeed, when an appellate court determines that it has a complete record before it, the court has the power to make final determinations. *Id.* That the Federal Circuit had the power to rule on the merits of Novo Nordisk's defense of lack of enablement in the context of a preliminary injunction is beyond controversy.

Numerous appellate courts, acting within the purview of Section 2106, have entered judgment on the merits after a preliminary injunction hearing. *See Chicago Observer, Inc. v. City of Chicago*, 929 F.2d 325, 329 (7th Cir. 1991) (reversing preliminary injunction and instructing lower court to enter judgment in defendant's favor because the plaintiff "has not suggested that it holds more evidence it could offer at trial and we cannot imagine what additional evidence could aid its cause."); *Glasgow, Inc. v. Federal Highway Administration*, 843 F.2d 130, 139 (3d Cir. 1988) (appellate court reversed district court's order granting permanent injunction and directed that the action be dismissed where district court's finding was error as a matter of law); *National Ass'n of Farmworkers Org. v. Marshall*, 628 F.2d 604, 622 (D.C. Cir. 1980) (appellate court decided case on review of district court's denial of a preliminary injunction because "the merits [we]re ready for review."); *Susquehanna*, 423 F.2d at 1086 (complaint dismissed where the record on a lengthy seven-day preliminary injunction hearing in the district court was complete).

Other appellate courts have reached similar results without specifically relying on Section 2106. *See Doe v. Sundquist*, 106 F.3d 702 (6th Cir. 1997); *Diginet, Inc. v. Western Union ATS, Inc.*, 958 F.2d 1388, 1395 (7th Cir. 1992) (court denied a permanent injunction on review of a preliminary injunction, reasoning that "[w]hen the appeal from a preliminary injunction brings up dispositive issues of law that can be decided without a trial, the sensible course is to convert the preliminary-injunction proceeding into a permanent-injunction proceeding and go directly to the merits").

VIII.

GENENTECH'S ARGUMENTS ARE NOT SUPPORTED BY THE CASES THEY CITE.

Genentech misplaces its reliance on *University of Texas v. Camenisch*, 451 U.S. 390 (1981), for its assertion that it was inappropriate for the Federal Circuit to reach the merits at the preliminary injunction stage, given the limited nature of the record. (Petition at 11). Whereas Genentech agreed that there was no need for additional evidentiary proceedings, including a trial, on the enablement issue, such was not the case in *Camenisch*, where this Court noted:

> The proceedings here bear the marks of the haste characteristic of a request for a preliminary injunction: the parties have relied on a short stipulation of facts, and even the legal theories on which the University has relied have seemed to change from one level of the proceedings to another.

451 U.S. at 398.

In the present case, the proceedings were lengthy and complete and the legal theories fully developed. *Camenisch* simply does not aid Genentech. *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809 (1986), is similarly inapposite. In *Dennison*, this Court found that the Federal Circuit did not explicitly apply a clearly erroneous standard to the district court's findings on obviousness, a question of fact, under Federal Rule of Civil Procedure 52(a). 475 U.S. at 811. In this case, however, the Federal Circuit made it clear that the '199 patent was not valid because it did not meet the statutory requirement of enablement. Its ruling was made as a matter of law on an issue of law on a complete record. (Appendix A at 1, 12-13).

Genentech's other citations also fail to serve its cause. In *Brown & Williamson Tobacco Corp. v. FTC*, 710 F.2d 1165 (6th Cir. 1983), *cert. denied*, 465 U.S. 1100 (1984), the district court refused to rule on the merits because it erroneously held that it lacked jurisdiction. However, the Sixth Circuit held that, like here, the record was sufficiently developed for it to reach the merits. 710 F.2d at 1172-1173. In *CES Publishing Corp. v. St. Regis Publications, Inc.*, 531 F.2d 11 (2d Cir. 1975), the Second Circuit held, on review of a preliminary injunction, that since the main Lanham Act claim was dismissible upon motion, the state law claims for trademark infringement should also be dismissed. In addition, even though the court did not have jurisdiction over the cross appeal, the court could dismiss it on the merits because, under this Court's precedents, "on appeal from a mere interlocutory order, the Circuit Court of Appeals might direct the bill to be dismissed if it appeared that the complainant was not entitled to maintain its suit." 531 F.2d at 15 (citing *Meccano, Ltd. v. John Wanamaker*, 253 U.S. 136, 140-141 (1920)). *Libertarian Party of Indiana v. Packard*, 741 F.2d 981 (7th Cir. 1984), is also similar to the present case. There, the Seventh Circuit held that "since the plaintiffs' claims largely involve questions of law, and since both parties have argued the

merits of these claims on appeal," the appellate court deemed it "appropriate . . . to consider the merits of the plaintiffs' constitutional claims." 741 F.2d at 986.

Genentech is wrong in contending that Judge Easterbrook's decision in *Chicago Observer*, 929 F.2d at 329, "adds nothing to the court's authority" because the parties there agreed to submit that controversy on papers. (Petition at 12, n.3). In fact, however, the Seventh Circuit in *Chicago Observer*, like the Federal Circuit here, in fact found that it could decide the case on the merits because the parties had no further evidence to offer at trial:

> The preliminary injunction must be reversed because the Observer has no chance of success on the merits. Indeed, the City is entitled to judgment without further ado. *The Observer has not suggested that it holds more evidence it could offer at a trial, and we cannot imagine what additional evidence could aid its cause* . . . Once it becomes clear that additional proceedings are pointless, the court should bring the case to a close.

929 F.2d at 329 (emphasis added).

Genentech's reliance on then Justice Rehnquist's dissent in *Moses H. Cone Memorial Hospital v. Mercury Const. Corp.*, 460 U.S. 1, 35 (1983) (Petition at 12-13), depends upon a misleading cropping of the passage therefrom. The sentence omitted from Genentech's quotation, but which directly follows and completes the paragraph, reads:

> The Court of Appeals did have before it the memoranda filed in the District Court but,

> contrary to the Court's intimation, ante, at 29, *this issue was not argued in the Court of Appeals*. *See* 656 F.2d 933, 948, n.1 (Hall J. dissenting) ("No one argued that this court should decide that issue").

460 U.S. at 36 (emphasis added). Thus, a proper quote from then Justice Rehnquist's dissenting opinion in *Moses H. Cone* would have revealed that the dissent was concerned that the issue decided by this Court was not argued below, a situation very different than this case. Here, the issue of enablement was "thoroughly ventilated" at the district court level, with multiple days of hearing, and was fully briefed and completely argued at the court of appeals level. Moreover, the majority opinion in *Moses H. Cone*, not cited by Genentech, held that because the court of appeals had full briefs and submissions on the issue before it, it was justified in issuing an order on the merits under 28 U.S.C. § 2106:

> Title 28 U.S.C. § 2106 gives a court of appeals some latitude in entering an order to achieve justice in the circumstances. . . . The Court of Appeals had in the record full briefs and evidentiary submissions from both parties on the merits of arbitrability, and held that there were no disputed issues of fact requiring a jury trial before a § 4 order could issue. Under these circumstances, the court acted within its authority in deciding the legal issues presented in order to facilitate the prompt arbitration that Congress envisaged.

460 U.S. at 29. Plainly, then, *Moses H. Cone* fully supports the Federal Circuit's reliance on Section 2106.

Genentech also argues that it has been deprived of a right to a jury trial on the enablement issue, relying on the dissent in *Newell Co., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 775 (Fed. Cir. 1988), *cert. denied*, 493 U.S. 814 (1989).[5] (Petition at 13). The *Newell* case concerned the standards for JNOV in deciding the obviousness issue, a mixed issue of law and fact. The *Newell* majority held that where a general jury demand is made, the demanding party:

> [H]as a right to a jury trial in an action at law, not a right to a jury verdict. A jury verdict need not be obtained and may be set aside under the common law principles incorporated into the Constitution where there is no fact issue . . . to decide. The authority of the judge to rule on issues of law during the course of proceedings is an essential element of a jury trial.

864 F.2d at 763. The *Newell* majority also held, that a mixed law/fact question, such as obviousness, "is ultimately a question of law decidable by the court in response to a motion for JNOV," and is "subject to independent plenary review by" the Federal Circuit. 864 F.2d at 764. So, too, is the issue of enablement. *See Moleculon Research Corp.*, *supra*.

Genentech's alternative arguments are equally unpersuasive. First, Genentech claims that the Federal Circuit's decision deprived it of due process, citing *Gellman v. State of Maryland*, 538 F.2d 603, 606 (4th Cir. 1976). (Petition at 11). In *Gellman*, the "perilously close . . . violation of due process" occurred because the defendants had not filed a responsive pleading nor

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5. The text of the Petition fails to state that Genentech is in fact relying on the dissent, and not the majority opinion, in *Newell*.

even filed, prior to the hearing, a motion to dismiss. 538 F.2d at 606. Hence, the facts of *Gellman* bear no resemblance to the present case whatsoever.

Finally, Genentech's reliance upon the notice requirement contained in Rule 65(a) of the Federal Rules of Civil Procedure is misplaced because Rule 65(a) only applies to consolidation by *trial courts*, not appellate courts. As Rule 65(a) does not apply, and Section 2106 has no statutory or common law notice requirement, whether or not Genentech had notice of the Federal Circuit's intention to make a determination of the legal issue of enablement is wholly irrelevant.

CONCLUSION

The enablement issued decided by the court below is not an exceptional issue requiring review by this Court. The Federal Circuit decided the issue as a matter of existing law and precedent and did not create new tests or standards. There is nothing in the Decision or record to indicate that the Decision will have an impact beyond the dispute between the parties. Moreover, the Federal Circuit correctly exercised its authority pursuant to 28 U.S.C. § 2106, after two comprehensive hearings on the enablement issue, to render a decision on the merits.

Respectfully submitted,

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